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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,012	04/13/2004	Micheal Patrick Dillon	R0130D-CON	4690
24372 7590 11/26/2007 ROCHE PALO ALTO LLC PATENT LAW DEPT. M/S A2-250 3431 HILLVIEW AVENUE PALO ALTO, CA 94304			EXAMINER STOCKTON, LAURA LYNNE	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 11/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,012	<b>Applicant(s)</b> DILLON ET AL.	
	<b>Examiner</b> Laura L. Stockton, Ph.D.	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on August 8, 2007 and November 8, 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 48 and 52-62 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48, 52 and 54 is/are allowed.
- 6) ☒ Claim(s) 53 and 55-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/22/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

**Claims 48 and 52-62 are pending in the application.**

### ***Continued Examination Under 37 CFR 1.114***

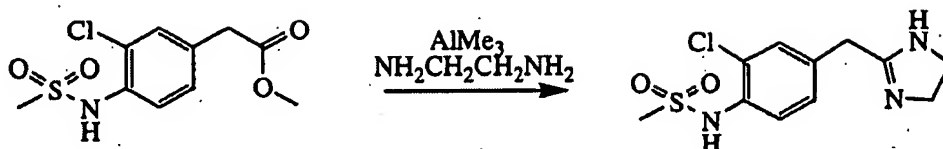
A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 8, 2007 has been entered.

### ***Election/Restrictions***

Applicant's election without traverse of Group I, and the species of Example 3 in step 4 on page 49 (reproduced below), in the reply filed on

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December 16, 2004 was acknowledged in a previous Office Action.

Step 4

The requirement was deemed proper and made FINAL in a previous Office Action.

Claims 53 and 55-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in the reply filed on December 16, 2004.

***Response to Amendment***

The following is a result of Applicant's current amendments to the claims. The Declaration under 37

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CFR 1.132 filed May 10, 2006 is sufficient to overcome the rejection of claims 48, 52 and 54 over Cournoyer et al. {U.S. Pat. 5,952,362} based upon the judicially created doctrine of obviousness-type double patenting and 35 USC 103 as set forth in the last Office Action.

Claims 48, 52 and 54 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 53 and 55-62, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on November 17, 2004 is hereby withdrawn.** In view of the withdrawal of the restriction

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requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Claim Objections***

Claim 53 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph  
of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-62 are rejected under 35 U.S.C. 112,  
first paragraph, as failing to comply with the  
enablement requirement. The claim(s) contains subject  
matter which was not described in the specification in  
such a way as to enable one skilled in the art to which  
it pertains, or with which it is most nearly connected,  
to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be  
considered in determining whether a disclosure meets  
the enablement requirement of 35 U.S.C. § 112, first  
paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,

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3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

***The nature of the invention***

Applicant is claiming a method for treating various diseases, conditions, symptoms or indications. See instant claim 55. From the reading of the specification (pages 13-14), it appears that Applicant is asserting that the embraced compounds, because of their mode action which involves the mediation of  $\alpha_1$  adrenergic receptors, would be useful for treating diseases, conditions, symptoms or indications such as sexual dysfunction, depression, dementia, Alzheimer's diseases, eating disorders, etc. Per the instant specification on page 13, "treating" embraces



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preventing the disease state, inhibiting the disease state, relieving the disease state, etc. Also per the specification on page 13, "disease state" embraces any disease, condition, symptom or indication.

***The state of the prior art and the predictability or lack thereof in the art***

The state of the prior art is that Alzheimer's disease (AD), for example, is an incurable neurodegenerative disease {see Thompson et al., Current Medicinal Chemistry, October 2002, 9(19), pages 1751-1762; and especially page 1753, column 2}. The existence of the obstacles discussed by Thompson et al. establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

***The amount of direction or guidance present and the presence or absence of working examples***

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There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the diseases, conditions, symptoms or indications claimed herein. That a single class of compounds can be used to prevent, treat, inhibit or relieve all of the diseases, conditions, symptoms or indications embraced by the claims is an incredible finding for which Applicant has not provided supporting evidence. Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating or preventing all of the diseases or conditions by administering the instant claimed compounds.

***The breadth of the claims***

The breadth of the claims is treating or preventing of all of the diseases, conditions, symptoms or indications generically embraced in the claim language.

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***The quantity of experimentation needed***

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities for each of the diseases and conditions found instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and conditions generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

***The level of the skill in the art***

Even though the level of skill in the pharmaceutical art is very high, based on the

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unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 is indefinite because claim 53 depends from cancelled claim 1.

In claim 53, it is unclear why there is a R<sup>13</sup> definition in the claim.

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***Allowable Subject Matter***


Claims 48, 52 and 54 are allowed over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

November 19, 2007